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PATENT APPLICATION
Attorney Docket No. 103477-0007

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Gary Mills et al.

Serial No. 10/549,330

Examiner: Brian Szmaj

Confirmation No. 6689

Filed: 12 September 2005

Group Art Unit: 3736

For: METHODS OF AND APPARATUS FOR DETERMINING FLUID VOLUME
PRESENCE IN MAMMALIAN TISSUE

Date: 30 March 2009

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Applicant respectfully requests review of the final claim rejections in the Office Action mailed on 17 November 2008 in the above-identified application. The assertions underlying each claim rejection in the office action are based upon clear legal and factual errors, and the cited references fail to teach or suggest at least one claim limitation of each presented claim, as detailed herein. As a result, the Final Office Action fails to establish a *prima facie* case of unpatentability under either 35 U.S.C. 102(e) or 35 U.S.C. §103(a) regarding any of the claims rejected therein. A Notice of Appeal is filed herewith.

Clear Factual and Legal Errors Regarding Rejections Under 35 §102(e)

Claims 1, 4-17 and 22-26 are rejected under 35 U.S.C. 102(e) as being anticipated by Alt (6,829,503 B2). Claims 12-26 are canceled under 37 C.F.R. 1.116(b)(1), and only claims 1 and 4-11 remain rejected over Alt.

The Examiner asserts that “on an external surface of the body” in claim 1 can include “any type of body, not just the skin”, and “any body, including body structures including a rib cage” as in Alt (Advisory Action). However, Claim 1 specifically recites, “a mammalian body”, and “positioning members of the first set of electrodes *on an external surface of the body*”. Applicant respectfully submits that the expressly described invasively implanted, *subcutaneous* electrodes of Alt fail to disclose applicant’s *non-invasive* electrodes positioned on an *external surface of the body*.

FIGS. 4 and 7 depict the recited “mammalian body 70”, (see also paragraphs 0023, 0026, 0043). Consistent with the described *non-invasive* method and apparatus, applicant depicts and describes an

"electrode assembly formed on a patient *skin patch*" (FIGS. 1A-1B, ¶ 0020), for application "*on the skin of a patient*" (¶ 0030), and having "an adhesive to secure it to *the body surface*" (¶ 0029). Thus, an artisan would recognize skin as the "external surface of the [mammalian] body" 70. Nowhere in the specification does applicant describe or depict an invasive surgically implanted, subcutaneous electrode.

The term "surface of the body" is well understood in the art, and *excludes* internal organs and rib cages. For example, the term 'exteriorization' means "a surgical procedure in which an organ is brought from its normal site *to the surface of the body*", (The Bantam Medical Dictionary, 2004, pages 242; emphasis provided). 'Skin' is defined in the relevant art as "the outer covering *of the body*" (The Bantam Medical Dictionary, 2004, page 602; emphasis provided); "the external limiting tissue layer of *an animal body*", (Merriam Webster's Collegiate Dictionary, 1995, page 1100; emphasis provided). One having ordinary skill would recognize that applicant's recited "electrodes on an external surface of the body" constitute electrodes on the surface of skin, and excludes Alt's implanted, subcutaneous electrodes.

Applicant's position in this regard does not require "reading a limitation from the specification into the claim". Rather, the recited limitation(s) requires only legally and factually proper interpretation consistent with applicant's expressly provided definitions, with their ordinary meanings in the relevant art, and consistent with the express, consistent, and exclusive non-invasive intent in the specification.

[R]equiring that any definition of claim language in the specification be express, is inconsistent with our rulings that the specification is 'the single best guide to the meaning of a disputed term,' and that the specification 'acts as a dictionary when it *expressly defines terms used in the claims or when it defines terms by implication.*' Phillips at 1321, citing *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed.Cir.1996); *Irdeto Access, Inc. v. Echostar Satellite Corp.*, 383 F.3d 1295, 1300 (Fed.Cir.2004)(emphasis provided).

Both Alt itself, referring to the 'exterior of the...body' (see below), and the Examiner's own description of Alt, expressly contradict the Examiner's assertion in the Final Office Action that applicant's recited claim limitations extend to electrodes positioned on 'a rib cage or organ', or that Alt's subcutaneous electrodes disclose 'electrodes positioned on an external surface of the body'.

First, Alt itself expressly states, "[T]he device is prevented from turning within its *subcutaneous pocket* which would otherwise position the...electrodes at *the wrong side*-namely, toward the *exterior of the patient's body*", (FIG. 2, Col. 2, lines 47-Col. 3, line 1). Applicant notes that the dotted line representation of the exterior "*of the...body as shown in FIG. 2*", (col 3, lines 4-5) is distinct and separate, positionally and structurally, from an 'external surface of the rib cage' in Alt. Alt's distinguishing and plain meaning use of 'the body' therein contradicts the assertion that Alt's rib cage discloses "the body".

Secondly, the Examiner acknowledges in the record that the device in Alt *is not placed* 'on an external *surface* of the rib cage', stating, "Alt discloses the implantation of the device such that the device is placed *in a pectoral muscle outside* the rib cage", (Final Office Action, page 10; emphasis provided).

Alt's express structural and functional distinction between the exterior of *the body* and the rib cage, *excludes* what the Examiner's assertion *requires* – that subcutaneously-positioned electrodes 'outside the rib cage' disclose electrodes positioned "on an external surface of the body". The Examiner's thusly contradictory assertion requires evidentiary support, but finds none in the record. The Examiner has not provided any evidence that invasively, surgically implanted subcutaneous electrodes in a pocket formed in a pectoral muscle outside, but not on an 'external surface of a rib cage', reasonably disclose applicant's recited "electrodes positioned on an external surface of the body".

"A claim is anticipated only if *each and every* element as set forth in the claim is found, either *expressly or inherently* described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of CA*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP §2131 (emphasis provided). One having ordinary skill in the relevant art would recognize that a device implanted in a *subcutaneous pocket* formed in a pectoral muscle by a surgeon, is not on *any external surface*. Therefore Alt completely fails to disclose at least one express limitation of claim 1, and fails to establish the required *prima facie* case.

Therefore, Examiner's assertions constitute clear legal and factual error, contrary to the substantial evidence provided in applicant's specification, exhibits, and arguments, contrary to the ordinary and expressly defined meanings of the terms used in the specification and in claim 1, and contrary to the Examiner's own statements and reference (Alt).

Further, applicant expressly, consistently, and *exclusively* describes that "[t]he present invention relates to...methods and apparatus that process *noninvasive* electrical bio-impedance measurements, (Paragraph 0001). "Methods and apparatus . . . process *noninvasively measured* electrical bio-impedance [sic] values", (Abstract). "What is needed are methods and apparatus that can *non-invasively* detect fluid shifts which could cause onset of shock. More particularly, methods and apparatus are needed that *non-invasively* measure electrical bio-impedance values", (§ 0011).

The term 'non-invasive', in the context of the applicants' specification, carries the plain meaning of, "*not involving penetration* (as by surgery or hypodermic needle) *of the skin* of the intact organism (~diagnostic techniques)", (Merriam Webster's Collegiate Dictionary, 1995, page 790; emphasis provided).

One having ordinary skill, in light of common knowledge in the art at the time of applicant's effective filing date, and consistent with the ordinary meanings of terms in claim 1 and the specification that enlightens its meaning, would interpret the recited "electrodes *on an external surface of the body*" to mean electrodes non-invasively placed on the skin of the subject's body.

In contrast to and directly inconsistent with applicant's non-invasive methods, apparatuses, and intent, Alt expressly, consistently, and unambiguously describes electrodes "*implanted in a subcutaneous pocket* formed by the surgeon *in the patient's chest*, under...*minimally invasive requirements*", (Col. 1,

lines 42-44)(see also FIG 2). An 'invasive' apparatus or procedure is one "involving entry into the living body (as by incision or by *insertion of an instrument*) (~diagnostic techniques)", (Merriam Webster's Collegiate Dictionary, 1995, page 616; emphasis provided), as Alt expressly describes and requires, and which the Examiner does not dispute.

One having ordinary skill in the relevant medical arts will recognize that subcutaneous implantation inherently and unavoidable requires an invasive breach of, and surgical implantation beneath, the external surface (skin) of a subject's body, and Alt expressly so describes. In light of applicant's expressly described non-invasive intent, and clearly recited and defined "electrodes on an external surface of the body", an artisan would not interpret the scope of applicant's recited limitation and described non-invasive method/apparatus to include invasively-placed electrodes beneath a subject's skin.

The Examiner, however, asserts that "[t]he current claim language can be interpreted as placing a device on an external surface of any kind of body", including "*a rib cage* [as in Alt], on an external surface of the skin, or even on an external surface of an organ". (31 December 2008 Advisory Action, page 2; emphasis provided). Alt's electrodes are on the concave side of a subcutaneously implanted curvilinear device, positioned outside and facing, but not on, the rib cage (see FIGS. 1-2, column 2, lines 47-64). Applicant's electrodes are on a "skin patch", (see citation above).

Thus, the Examiner's assertion constitutes both clear factual and clear legal error. Applicant's consistently described non-invasive methods and apparatus inherently exclude Examiner's assertions. Nor does applicant's disclosure provide 35 U.S.C. § 112, first paragraph support for the Examiner's asserted claim scope.

Applicant acknowledges that the Office may give the claims their broadest reasonable interpretation (MPEP 2111). But this does not mean claims can reasonably be interpreted "as broad as possible", as asserted by the Examiner (Advisory Action, page 2; emphasis provided). The scope of interpretation must be *consistent with the specification*. "The claims are directed to the invention that is described in the specification; they *do not have meaning* removed from the context from which they arose." (*Phillips* at 1316, citing *Netword, LLC v. Centraal Corp.*, 242 F.3d 1347, 1352 (Fed.Cir.2001)).

Yet, the Examiner has *not placed in the record any intrinsic or extrinsic evidence* supporting the assertion that applicant's limitation "external surface of the body" can reasonably include "any type of body" (Advisory Action, page 2). The Examiner has not issued a 35 U.S.C. § 112 rejection for lack of descriptive support in applicant's specification for the Examiner's asserted expansive limitation. But the Examiner also has not indicated in the record any descriptive support in applicant's specification for, or consistent with, the asserted interpretation, which necessarily includes invasive methods.

Because the Examiner has not placed any evidence in the record, the Examiner appears to be taking Official Notice of facts beyond the record regarding what is known in the art.

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If such notice is taken . . . [t]he examiner must provide *specific factual findings* predicated on *sound technical and scientific reasoning* to support his or her conclusion of common knowledge. See *Soli*, 317 F.2d at 946, 37 USPQ at 801; *Chevenard*, 139 F.2d at 713, 60 USPQ at 241. (MPEP 2144.03)(Emphasis provided)

"[O]fficial notice has been taken of a fact that is asserted to be "common knowledge" without specific reliance on documentary evidence where the fact noticed was readily verifiable, *such as when other references of record supported the noticed fact*, or where there was *nothing of record to contradict it*.

The asserted 'facts' are directly contradicted by Examiner's own art, and are inconsistent with applicant's non-invasive descriptions, substantial evidence (in the record) of the ordinary and plain meanings of the recited terms, and applicant's express use of the recited claim terms in the specification.

Therefore, for at least the numerous reasons discussed above, applicant respectfully submits that Alt fails to provide a *prima facie* basis for the asserted rejection of claim 1, and the rejection of applicant's claim 1 over Alt is improper. Applicant requests withdrawal of final rejection from claim 1, as well as claims 4-11 which depend therefrom, and allowance of claims 1 and 4-11 without further delay.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Alt as applied to claim 1 above, and further in view of Takehara et al (2002/0022787 A1)(Takehara) in view of Duong et al (6,740,518 B1)(Duong). Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Alt as applied to claim 1 above, and further in view of Baura et al (6,561,986 B2)(Baura).

However, the rejections of claims 2 and 3 both rely upon the errantly asserted reading into Alt of "electrodes positioned on an external surface of the body", as discussed above. Inasmuch as Takehara, Duong, and Baura are not asserted to, and do not, correct the failures of Alt, whether individually or when combined as asserted, applicant respectfully submits that no *prima facie* case for rejection under 35 U.S.C. § 103(a) is established in the Final Office Action. Therefore, applicant respectfully requests withdrawal of the rejections from claims 2 and 3, and allowance of the same without delay.

Conclusion

In light of the arguments set forth herein, applicant respectfully submits that all rejections asserted in the Final Office Action are shown herein to be improperly based upon clear factual and legal errors, and that a *prima facie* case is not established to support the rejections. Applicant therefore respectfully requests that all claims be allowed without undue delay.

I hereby certify that this correspondence is being transmitted to the U.S. Patent and Trademark Office via facsimile number 571-273-8300 on the following date: March 30, 2009



Nicholas Weintraub

Respectfully submitted,

/Patrick D. Boyd/

Patrick D. Boyd
Reg. No. 54,671
Customer No. 35940